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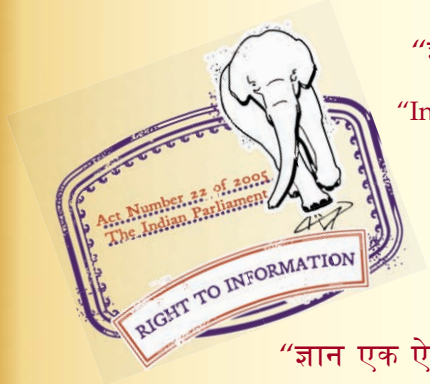

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IS : 12050 - 1986

(Reaffirmed 2001)

Indian Standard

SPECIFICATION FOR STERILE HYPODERMIC SYRINGES WITH NEEDLE ATTACHED FOR SINGLE USE

UDC 615'475'3

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

Gr5

December 1987

Indian Standard

SPECIFICATION FOR STERILE HYPODERMIC SYRINGES WITH NEEDLE ATTACHED FOR SINGLE USE

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Indian Standard

SPECIFICATION FOR STERILE HYPODERMIC SYRINGES WITH NEEDLE ATTACHED FOR SINGLE USE

0. FOREWORD

0.1 This Indian Standard was adopted by the Indian Standards Institution on 11 November 1986, after the draft finalized by the Medical Glass Instruments and Appliances Sectional Committee had been approved by the Consumer Products and Medical Instruments Division Council.

0.2 This standard deals with products primarily intended for use with human beings and provides performance requirements, but permits some variations of design and of the methods of packaging and sterilization by individual manufacturers.

0.3 Materials to be used for the construction of sterile syringes for single use are not specified in detail as their selection will depend to some extent upon the design, process of manufacture and method of sterilization employed by individual manufacturer.

0.4 The materials should be compatible with injection fluids included in the Indian Pharmacopoeia and where this is not the case, the attention of the user should be drawn to the exception by labelling the unit container.

0.5 The majority of injections are in aqueous media. Such media are not known to give problems. It is usual for non aqueous injections either to be formulated in ester-type solvent, or the active ingredient itself may be fluid. Depending upon the duration of contact, some of these fluids may react to a varying extent with syringe components. It is difficult to specify a universally acceptable method of test for incompatibility. However, a list of solvents and other fluids selected from the Indian pharmacopoeia to represent materials used in injections is provided in Appendix E together with a simple recommended test which may be used to detect visible or functional incompatibility between syringes and injectible fluid.

0.6 Some solvents not included in the Indian Pharmacopoeia are used by Pharmaceutical manufacturers. Such solvents should be tested by the manufacturer of the injection for any possible incompatibility with the materials frequently used in syringe manufacturing. Where incompatibility exists, the injection should be suitably labelled.

0.7 The above mentioned test procedure can be regarded only as means of proving indications of incompatibility of syringes with the injectible

fluids generally used. The only conclusive test should be of an individual injectible fluid with a specific syringe.

0.8 Tests for freedom from pyrogenic material and abnormal toxicity and certain other requirements as included in IS : 10258-1982* shall be complied with.

0.9 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS : 2-1960†. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard specifies requirements for sterile hypodermic syringes with needle attached, for single-use.

1.2 Sterile hypodermic syringes with needle attached, specified in this standard, are intended for use immediately after filling and are not intended for containing fluids or samples over extended periods, as for example, in perfusion pumps.

1.3 This Indian Standard does not cover the requirements for insulin syringes for single use.

2. TERMINOLOGY

2.0 For the purpose of this standard, the nomenclature as given in Fig. 1 and 2, and the following definition shall apply.

2.1 Permanently Attached Needle — Hypodermic needle which remains attached to the syringe. Since it is not intended that the attached needle be removed, it may be attached by means other than by a 6 percent conical taper fitting, for example, the needle cannula may be permanently bonded to the syringe barrel.

3. MATERIALS

3.1 The materials used in the construction of syringes shall be suitable for their intended use and the process to be used for their sterilization.

3.2 The materials used shall not cause the syringes to be detrimentally affected, physically or chemically, by the normal use of injectible preparations.

*Specification for sterile hypodermic syringes for single use.

†Rules for rounding off numerical values (*revised*).

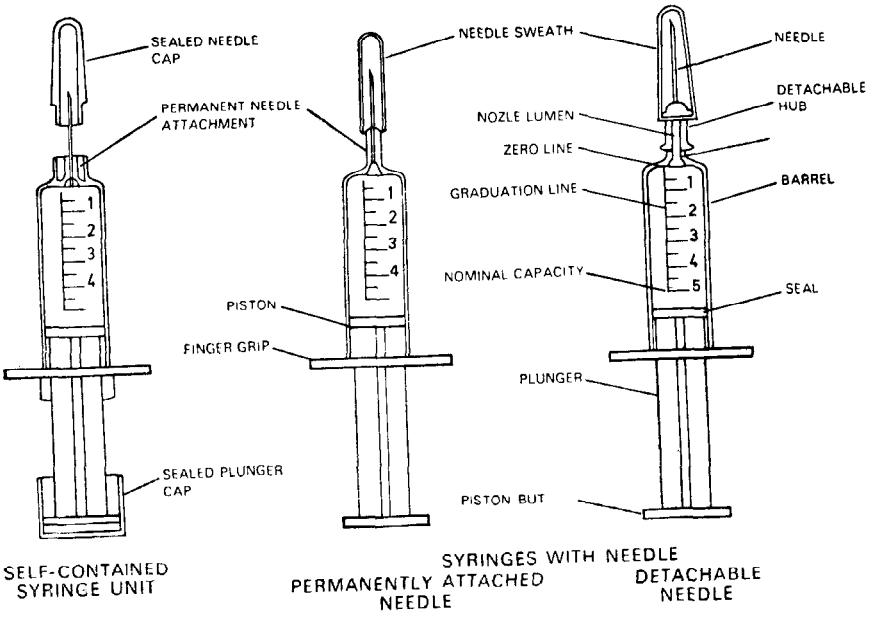


FIG. 1 SCHEMATIC REPRESENTATION OF HYPODERMIC SYRINGE WITH NEEDLE ATTACHED FOR SINGLE USE, TYPICAL

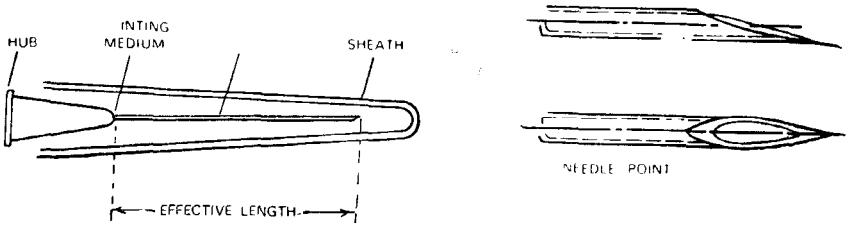
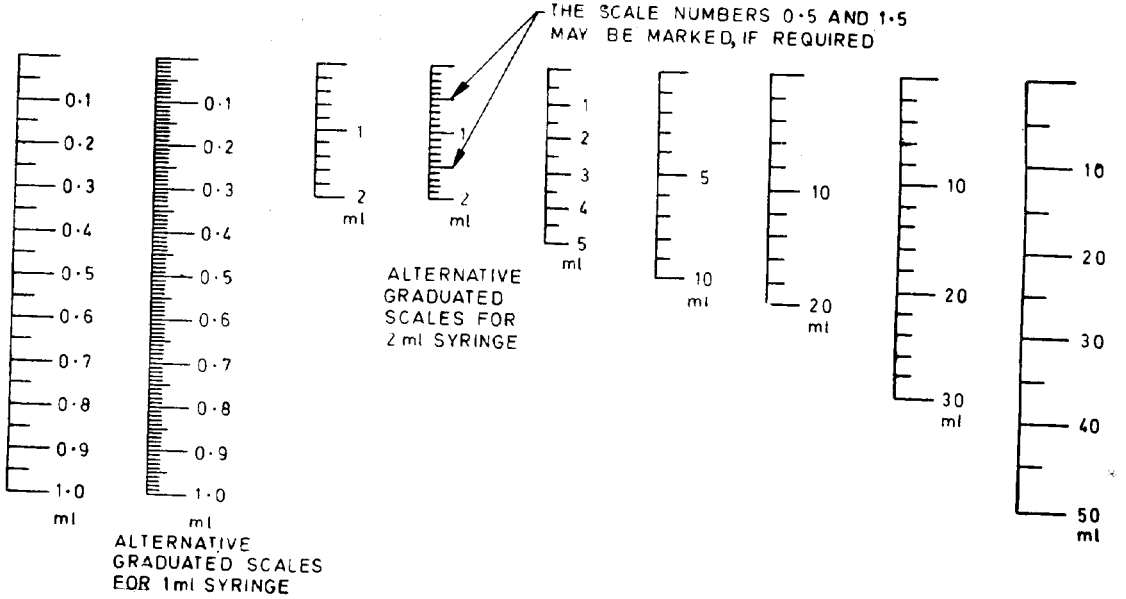


FIG. 2 NEEDLE WITH HUB FOR HYPODERMIC SYRINGE WITH NEEDLE ATTACHED FOR SINGLE USE, TYPICAL

4. CAPACITY LENGTH OF SCALE AND SCALE INTERVAL OF SYRINGES WITH NEEDLE ATTACHED

4.1 The nominal capacity, the tolerance on graduated capacity, minimum length of the scale and scale interval are shown in Table 1 and Fig. 3. However, other capacities and dimensions may also be permitted as agreed to between the purchaser and the supplier.



NOTE — The vertical line of the scale may be omitted.

FIG. 3 SCALE GRADUATIONS OF HYPODERMIC SYRINGES FOR SINGLE USE

TABLE 1 NOMINAL CAPACITY, TOLERANCE ON CAPACITY, MINIMUM LENGTH OF SCALE AND SCALE INTERVAL

(*Clause* 4.1)

Nominal Capacity of Syringe	Tolerance on Any Graduated Capacity Exceeding Half the Nominal Capacity	Minimum Length of Scale	Scale Interval
(1)	(2)	(3)	(4)
ml	percent	mm	ml
1	± 5	57	0·05 or 0·01
2	± 5	27	0·2 or 0·1
5	± 4	36	0·5
10	± 4	44	1
20	± 4	52	2
30	± 4	67	2
50	± 4	75	5

5. SIZE DESIGNATION OF ATTACHED NEEDLE

5.1 The size of the attached hypodermic needle shall be designated by the following:

a) Nominal external diameter of needle cannula expressed in millimetres; and

b) Nominal effective length of needle cannula expressed in millimetres, to be measured from the tip of the point to the joint with the hub or, when cannula is permanently bonded; to the joint with syringe barrel.

Example — The size of a needle with the nominal external diameter of the needle cannula as 0·8 mm and with the nominal effective length of the needle cannula as 40 mm shall be designated as 0·8 × 40.

6. RANGE OF SIZES AND COLOUR CODE OF ATTACHED NEEDLES

6.1 The nominal external diameter and the preferred nominal effective length of the needle cannula shall be in accordance with Table 2.

6.2 The nominal diameter of the needles shall be identified by colour coding in accordance with Table 2, applied to the unit container and/or part of the needle assembly such as the needle hub or the sheath.

6.3 The limits of external diameter and the minimum bore of the needle cannula shall be as given in Table 3. Tolerance on the nominal effective length of the needle cannula shall be as under:

Nominal Length	*Tolerance*
mm	mm
Up to 25	± 1
Above 25	± 1·5

TABLE 2 PREFERRED SIZES AND COLOUR CODE OF ATTACHED NEEDLE CANNULA

(*Clauses* 6.1 *and* 6.2)

Nominal External Diameter, mm	Colour Code	Preferred Nominal Effective Length, mm					
		12	16	25	30	40	50
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
0·45	Light Brown	×					
0·5	Orange	×	×				
0·6	Blue			×	×		
0·7	Black			×	×	×	
0·8	Green			×		×	×
0·9	Yellow			×		×	
1·1	Cream			×	×	×	×
1·1 (thin walled)	Cream					×	

NOTE — × indicates the preferred length(s) for a particular external diameter.

TABLE 3 LIMITS OF EXTERNAL DIAMETER AND MINIMUM BORE OF ATTACHED NEEDLE CANNULA

(*Clause* 6.3)

Nominal Diameter	External Diameter		Minimum Bore of Needle
	Min	*Max*	
(1)	(2)	(3)	(4)
mm	mm	mm	mm
0·45	0·44	0·47	0·24
0·5	0·5	0·53	0·24
0·6	0·62	0·65	0·32
0·7	0·7	0·73	0·39
0·8	0·8	0·83	0·4
0·9	0·86	0·96	0·5
1·1	1·03	1·1	0·6
1·1 (thin walled)	1·03	1·1	0·7

7. FLANGE OF BARREL OR FINGER GRIPS

7.1 The open end of the barrel shall be provided with finger grips or flange which shall ensure that syringe shall not roll when it is placed on a flat surface with the scale uppermost and at an angle of 10° to the horizontal.

7.2 Finger grips or flange shall be of adequate size, shape and strength for the intended purpose and shall enable the syringe to be held securely during use. Finger grips or flange shall be free from flash and sharp edges.

8. PISTON

8.1 Design of the piston and piston button of the syringe shall be such that when the barrel is held in one hand the piston can be depressed by the thumb of that hand. The piston shall not become detached from the plunger under aspiration conditions of normal use.

8.2 The projection of the piston and the configuration of the piston button shall be such as to enable the piston to be withdrawn without difficulty.

8.3 There shall be clearly visible and defined edge serving as fiducial line at the end of the piston for determining the capacity corresponding to any scale reading on the syringe. The fiducial line shall be in contact with the inner surface of the barrel.

8.4 The outer end of the piston shall be of suitable size to allow finger pressure to be applied to the piston for the ejection of liquid from the syringe.

8.5 The piston fit in the barrel shall be such that it slides smoothly throughout the graduated length of the barrel.

9. LEAKAGE TEST

9.1 Liquid Leakage Past the Syringe Piston and at the Syringe Needle Union During Compression — There shall be no leakage beyond the piston seals and at the syringe needle union when tested in accordance with Appendix B.

9.2 Air Leakage Past the Syringe Piston and at the Syringe Needles Union During Aspiration — There shall be no continuous formation of bubble rising from the syringe/needle tube joint when tested in accordance with Appendix C. Bubbles formed during the first 5 seconds shall be ignored.

10. LIMITS FOR EXTRACTABLE MATTER

10.1 The syringe and needle assembly shall be capable of satisfying the chemical tests for extractable matter in accordance with procedures given in the Indian Pharmacopoeia.

10.2 Limits for Acidity or Alkalinity — The *p*H of the extract shall be determined with a laboratory potentiometeric *p*H meter and using a general purpose electrode in accordance with the procedure given in the Indian Pharmacopoeia.

10.2.1 The *p*H valuc of the extract prepared by the procedure given in **A-2** and **A-3** of Appendix A shall be within one unit of *p*H of the control fluid.

10.3 Limits for Extractable Metals — An extract prepared in accordance with Appendix A shall contain not more than a combined total of five parts per million of lead, tin, zinc and iron tested by a recognised micro-analytical method, for example by an atomic absorption method. The cadmium content of the extract shall be less than 0·1 parts per million.

11. NEEDLE ATTACHMENT

11.1 Permanently Attached — Where the needle tube is permanently bonded to the syringe barrel (directly or indirectly) or to a attached needle hub, it shall be capable of satisfying the test requirements given in **12.1**.

11.2 Detachable Needle Hub — The female conical fitting of the needle hub shall comply with the dimensions shown in IS : 3234 (Part 2)-1986*.

11.2.1 The male conical (Luer) fitting of the syringe nozzle shall comply with the dimensions shown in IS : 3234 (Part 2)-1986*.

11.3 Position of Needle Attachment on End of Barrel

11.3.1 On syringes of graduated capacity of 1 ml and 2 ml, the needle attachment shall be situated centrally, that is, co-axial with the barrel.

11.3.2 On syringes of graduated capacity of 5 ml and greater, the needle attachment may be situated either centrally or eccentrically.

11.3.3 Where the attachment is eccentrical, it shall be vertically below the axis of the barrel when the syringe is lying on a flat surface with the scale uppermost and the distance between the axis of the tip and the nearest point on the internal surface of the bore of the barrel shall be of not greater than 4 mm.

12. TEST REQUIREMENTS FOR NEEDLES ASSEMBLY

12.1 Bond Between Hub/Syringe Barrel and Needle Tube — The union of the hub/syringe barrel and needle tube shall not be broken by a force of the magnitude given in Table 4 applied as 'Push' and 'Pull' in the direction as of the axis of the needle.

12.2 Patency of Lumen — A stainless steel stilette of the appropriate diameter selected from Table 5 shall pass freely through the attachment needle assembly.

12.2.1 Alternatively, the lumen shall satisfy a water flow rate test in which flow rate shall be not less than 80 percent of that of a needle of equivalent size having the minimum bore in accordance with Table 3. The water pressure during the test shall not exceed 1 kgf/cm^2.

*Specification for conical fittings with a 6 percent (Luer) taper for syringes, needles and other medical equipment: Part 2 Lock fittings (*second revision*).

TABLE 4 TEST FORCE FOR BOND BETWEEN HUB OR SYRINGE BARREL AND NEEDLE TUBE

(*Clause* 12.1)

NOMINAL DIAMETER	FORCE
mm	N
0·45	22·5
0·5	22·5
0·6	30·0
0·7	35·0
0·8	45·0
0·9	55·0
1·1	70 0
1·1 (thin walled)	70·0

TABLE 5 SIZE OF STILETTE TO TEST PATENCY OF LUMEN

(*Clause* 12.2)

NEEDLE NOMINAL DIAMETER	DIAMETER OF STILETTE
mm	mm
0·45	0·18
0·5	0·18
0·6	0·25
0·7	0·30
0·8	0·40
0·9	0·48
1·1	0·58
1·1 (thin walled)	0·70

13. DEAD SPACE VOLUME

13.1 The volume of liquid contained in the barrel and the nozzle when the piston is fully inserted shall be in accordance with Table 6, when tested, as described in Appendix D.

TABLE 6 MAXIMUM DEAD SPACE

NOMINAL SIZE OF SYRINGE	MAXIMUM VOLUME OF DEAD SPACE
ml	ml
1	0·07
2	0·07
5	0 07
10	0·10
20	0·15
30	0·17
50	0·20

14. PACKING

14.1 Syringe with permanently attached needle.

14.1.1 *Unit Container*

14.1.1.1 Each hypodermic syringe with permanently attached needle shall be:

a) sealed in a unit container; and

b) designed as a self-contained unit such that the sterility of the interior (which includes the needle) is maintained by protective caps which are sealed to, and removable from the syringe.

14.1.1.2 The materials and design of the unit container of self-contained syringe unit shall be such as to ensure:

a) maintenance of sterility of the contents of the unit container or of the interior of the self-contained syringe unit under dry, clean and adequately ventilated storage conditions;

b) adequate protection of the contents of the unit container or of the self contained syringe unit during normal handling, transit and storage; and

c) the material and design of the unit container shall be such as to ensure minimum risk of contamination of the contents of the unit container during removal from container.

14.1.2 *Outer Container* — A convenient number of unit containers of self-contained syringe units shall be packed in an outer container or containers which shall be sufficiently robust to protect the contents during transit and storage.

14.2 Syringe with Detachable Needle

14.2.1 *Unit Container* — Each hypodermic syringe and attached needle shall be sealed in a unit container. The material and design of this container shall be such as to ensure the following:

a) Maintenance of sterility of the contents of the unit container under dry, clean and adequately ventilated storage conditions;

b) Adequate protection of the contents of the unit container during normal handling, transit and storage; and

c) The material and design of the unit container shall be such as to ensure minimum risk of contamination of the contents of the unit container during removal from the container.

14.2.2 *Outer Container* — A convenient number of unit containers shall be packed in an outer container which shall be sufficiently robust to protect the contents during transit and storage.

15. STERILITY

15.1 The contents of the unit container (*see* **14.1.1** and **14.2.1**) shall be sterile and shall be capable of satisfying the sterility test requirements of the Indian Pharmacopoeia or IS : 10150-1981*.

16. MARKING OF CONTAINERS

16.1 Self-contained Syringe Unit — The syringe unit shall be marked with the following:

a) Syringe capacity and needle size;

b) The words 'STERILE INTERIOR';

c) The words 'DESTROY AFTER SINGLE USE' or equivalent;

NOTE — Use of the term 'disposable' is not acceptable.

d) A warning of solvent incompatibility, for example, 'Not to be used with paraldehyde';

e) The name and/or trade-mark of the manufacturer or supplier; and

f) An identification reference to the batch or date of manufacture.

16.1.1 Where all the information specified in **16.1** (a) to (f) does not appear on the self-contained syringe unit, each unit shall carry the information specified in items (a), (b) and (e), and all the information from (b) to (f) inclusive with a description of the contents and a warning to check the integrity of the protective cap seals shall appear on the first level of packaging of the syringe unit.

16.2 Unit Container — The unit container shall be marked with the following:

a) Description of contents;

b) The word 'STERILE';

c) The words 'DESTROY AFTER SINGLE USE' or equivalent;

NOTE — Use of the term 'disposable' is not acceptable.

d) A warning of solvent incompatibility, for example, 'Not to be used with paraldehyde';

e) The name and/or trade-mark of the manufacturer or supplier; and

f) An identification reference to the batch or the date of manufacture.

*Guide for sterilization of medical products.

16.3 Outer Container — The outer container shall be marked with the following:

a) Description of contents, including the words STERILE and FOR SINGLE-USE or the equivalent.

b) Warning to check the integrity of each unit container or each syringe unit.

c) An identification reference to the batch as for item **16.1**(f) and **16.2**(f) and date (month and year) of sterilization.

d) Name, and/or trade-mark, and address of manufacturer or supplier.

16.4 The syringe unit may also be marked with the Standard Mark.

NOTE — The use of the Standard Mark is governed by the provisions of the Bureau of Indian Standards Act 1986, and the Rules and Regulations made thereunder. The Standard Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well defined system of inspection, testing and quality control which is devised and supervised by BIS and operated by the producer. Standard marked products are also continuously checked by BIS for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

APPENDIX A

(*Clauses* 10.2.1 *and* 10.3)

PREPARATION OF EXTRACTS

A-1. EXTRACTION FLUID, TYPE 1

A-1.1 Extraction Fluid (1) — Extraction shall be carried out with sterile pyrogen free saline solution containing 9 g/l of sodium chloride of recognized analytical quality in freshly prepared distilled water.

A-2. EXTRACTION FLUID, TYPE 2

A-2.1 Extraction Fluid (2) — Extraction shall be carried out with freshly prepared sterile distilled water.

A-3. METHOD

A-3.1 At least three syringes with attached needle shall be filled to the nominal capacity with the extraction fluid and maintained at a temperature of $37 \begin{smallmatrix} +3^{\circ}C \\ -0^{\circ}C \end{smallmatrix}$ for 8 hours. The containers shall be combined in a suitable container made from borosilicate glass.

A-3.2 Where needles are detachable, at least 25 needles shall be immersed in 250 ml extraction fluid in a suitable container made from borosilicate glass and maintained at a temperature of 37 $^{+3^\circ C}_{-0^\circ C}$ for one hour.

APPENDIX B

(*Clause* 9.1)

TESTING FOR LIQUID LEAKAGE PAST THE SYRINGE PISTON AND AT SYRINGE NEEDLE UNION DURING COMPRESSION

B-1. TEST METHOD

B-1.1 Procedure

B-1.1.1 Draw into the syringe through the needle a volume of water exceeding the graduated capacity of the syringe. Avoid wetting the syringe/needle union.

B-1.1.2 Expel air.

B-1.1.3 Adjust the volume of water in the syringe through the needle to the maximum graduated capacity.

B-1.1.4 Seal the needle tip.

B-1.1.5 Apply the side load to the push botton at right angles to the plunger to swing the plunger radially about the piston seal(s) with a force as given below (the plunger shall be oriented to permit the maximum deflection from the axial position).

Nominal Size of Syringe	*Force*
ml	N
1	0·245
2	0·981
5	1·961
10	2·942
20	2·942
30	2·942
50	2·942

B-1.1.6 Apply an axial force to the syringe so that a pressure is generated by the relative action of the piston and barrel of 300 kPa gauge below 20 ml and 200 kPa gauge for 20 ml size and larger sizes, and maintain the pressure for 30 seconds.

APPENDIX C

(*Clause* 9.2)

TESTING FOR AIR LEAKAGE PAST THE SYRINGE PISTON AND AT THE SYRINGE NEEDLE UNION DURING ASPIRATION

C-1. TEST FOR AIR LEAKAGE PAST THE PISTON DURING ASPIRATION

C-1.1 Procedure — The test shall be conducted using apparatus as illustrated in Fig. 4 in accordance with the procedure given in **C-1.1.1** to **C-1.1.5**.

C-1.1.1 Draw into the syringe through the needle a volume of recently boiled and cooled water of not less than 25 percent of the graduated capacity.

C-1.1.2 With the needle uppermost withdraw the plunge raxially until the fiducial line is at the maximum graduated capacity and damp the plunger in this position as illustrated in Fig. 4.

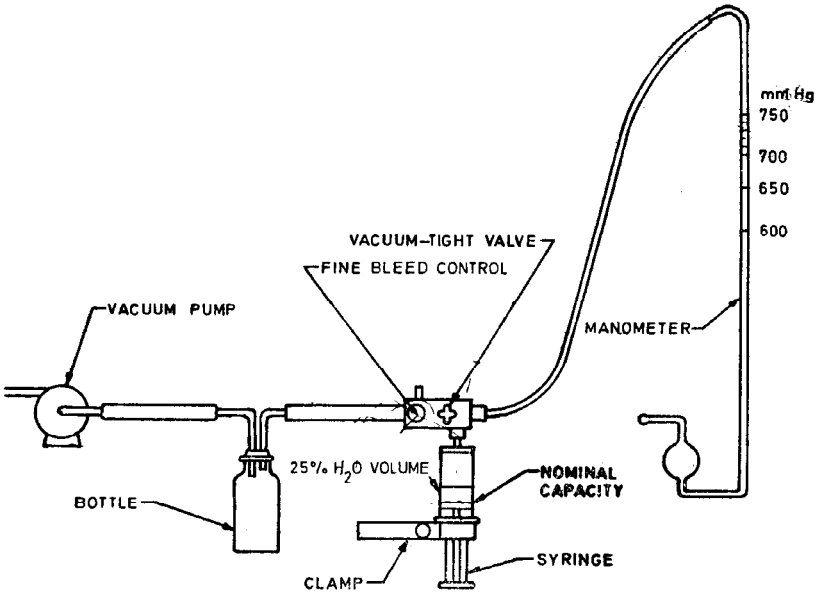


FIG. 4 APPARATUS USED IN ASPIRATION TEST

C-1.1.3 Push the rubber diaphragm on to the needle to make a leak-proof connection.

C-1.1.4 Switch on the vacuum pump with air bleed control open.

C-1.1.5 Adjust the bleed control so that a gradual increase in vacuum is obtained and a manometer reading of 88 kPa (660 mm Hg) is reached.

C-1.2 Acceptance Criteria

C-1.2.1 There shall be no leakage of air past the piston up to and including a manometer reading of 88 kPa (660 mm Hg).

C-1.2.2 As a further check the syringe and manometer assembly shall be isolated by a vacuum tight valve and the manometer reading observed for 60 seconds. A graduated fall in manometer will indicate the ingress of air into the assembly.

C-2. TEST FOR AIR LEAKAGE AT SYRINGE NEEDLE UNION DURING ASPIRATION

C-2.1 Procedure

C-2.1.1 Draw into the syringe through the needle a volume of recently boiled and cooled water exceeding 25 percent of the nominal graduated capacity of the syringe.

C-2.1.2 Avoid wetting the syringe needle union.

C-2.1.3 Expel air.

C-2.1.4 Adjust the volume of water in the syringe to 25 percent of the nominal graduated capacity.

C-2.1.5 Seal the needle tip.

C-2.1.6 With the needle downwards withdraw the piston to the nominal graduated capacity.

C-2.1.7 Hold for 15 seconds.

APPENDIX D

(*Clause* 13.1)

DETERMINATION OF DEAD SPACE

D-1. METHOD

D-1.1 The syringe with needle attached shall be weighed empty and then filled to the total graduated capacity with distilled water, care being taken to expel all air bubbles and for the level of the water meniscus to

coincide with the end of the lumen. After the water is expelled from the syringe through the needle with the piston fully depressed, the outer surface of the syringe and attached needle shall be wiped dry. The syringe and attached needle and residual water shall then be weighed.

D-2. The difference in mass in grams shall be taken as equivalent to the volume in millilitres of the dead space in the syringe and attached needle.

APPENDIX E

(*Clause* 0.5)

RECOMMENDED METHOD OF TESTING FOR INCOMPATIBILITY BETWEEN SYRINGES AND INJECTION FLUIDS

E-1. SELECTION OF SOLVENTS

E-1.1 A selection of solvents and other fluids used in preparations for injection, and suitable for testing syringes for compatibility, as listed in **E-1.2** below is recommended as providing ready means of indicating the compatibility between syringes and materials used in injection fluids.

E-1.2 A Selection of Solvents and Other Fluids Used in Injection Fluids

a) Water,
b) Ethanol +5 percent water,
c) Ethyl oleate,
d) Propylene glycol +10 percent water,
e) Arachis oil,
f) Arachis oil +10 percent benzyl alcohol,
g) Archis oil +10 percent benzyl benzoate,
h) Iodized oil (poppyseed oil with 37 to 39 percent iodine),
j) Iophendylate, and
k) Paraldehyde.

E-2. METHOD OF TEST

E-2.1 Test to Detect Visible and Functional Incompatibility Between Syringes and Injectible Fluids — Fill two syringes with test fluids invert and retain at 27 ± 3°C. After 1 hour, expel the fluid from syringes. There should be no significant increase in the force required to move their plungers. Wipe all surfaces with tissue paper and note any change in appearance, opacity or colour that has occurred in either of the syringes or the expelled fluid. Evidence of incompatibility may also be indicated by swelling of rubber and/or stress cracking, etching, stickiness or softening of the interior surface of the syringe barrel(s).

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IS 12050 : 1986 SPECIFICATION FOR STERILE HYPODERMIC SYRINGES WITH NEEDLE ATTACHED FOR SINGLE USE

(*Page* 5, *clause* **4.1**) — Add the following new clause after **4.1**:

"**4.2** Other dimensions of the syringes which are not covered under **4.1**, shall conform to IS 10258 : 1982 'Sterile hypodermic syringes for single use'."

(*Page* 13, *clause* **16.2**) — Add the following after (f):

' g) The mode of sterilization.'

(MHD 12)

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